

In the Claims:

Please amend the claims as follows:

1. (currently amended) A method for determining, between two times, a change in a level of concentration of an analyte present in a source, comprising:

providing multiple unitary test devices, each unitary test device including a plurality of regions, each region responsive at a different sensitivity level to indicate presence of the analyte in the source;

bringing a first sample from the source into contact with a first of the unitary test devices at a first time to induce, at the first time, a visually observable response in one or more regions of the first test device based on the source containing a minimum level of analyte concentration; and

subsequently bringing a second and different sample from the same source into contact with a second of the unitary test devices at a second time to induce at the second time, a visually observable response in one or more regions of the second test device based on the source containing a minimum level of analyte concentration; and

comparing a visually observable response induced in the first test device at the first time directly with a visually observable response induced in the second test device at the second time to provide information about a change in the level of analyte concentration between the two times wherein the change is determined based on capillary flow of each sample from a sample receiving region on one of the first or second test devices to one or more of the plurality of regions on the same test device and the response on each device is based on an amount of binding of an antigen and an antibody to form complexes.

2 – 9. (canceled)

10. (currently amended) A method for monitoring changes in analyte level of a source, comprising:

providing first and second lateral flow test units each of the type which includes a receiving zone for fluid samples separated from two or more regions, each region responsive to analyte migrating from the receiving zone by capillary flow into the region, the two or more regions on each test unit defining multiple measurably distinguishable sensitivity levels each distinguishable sensitivity level indicative of a different amount of analyte in the source;

providing first and second test units,

the first test unit including a first region thereon responsive to the presence of analyte in the source at a first of the sensitivity levels; and a second region responsive to presence of analyte in the source at a second of the sensitivity levels measurably distinguishable from the first of the sensitivity levels, wherein the first and second regions of the first test unit are responsive by binding an antigen and an antibody in order to identify presence of analyte in the source.

the second test unit including a first region thereon responsive to the presence of analyte in the source at the first of the sensitivity levels and a second region responsive to presence of analyte in the source at the a second of the sensitivity levels measurably distinguishable from the first of the sensitivity levels, wherein the first and second regions of the second test unit are responsive by binding an antigen and an antibody in order to identify presence of analyte in the source;

providing a first sample from the source at a first time;

bringing the first sample into contact with the receiving zone of the first unit to allow the first region thereon to receive a portion of the first sample by capillary flow from the receiving zone and provide an indication as to whether analyte is present in the first sample at at least the first of the sensitivity levels;

providing a second sample from the source at a second time subsequent to providing the first sample; and

bringing the second sample into contact with the receiving zone of the second unit to allow the first and second regions thereon to receive a portion of the first sample by capillary flow from the receiving zone and provide an indication as to whether analyte is present in the second sample at at least one of the first and second sensitivity levels,

wherein a difference between visually observable responses induced in the first test device at the first time and induced in the second test device at the second time, each based on binding of an antigen and an antibody, provides information about a change in the level of analyte concentration present in the source between the two times, wherein indications of presence of analyte in the first sample and indications of presence of analyte in the second sample provide evidence as to whether there has been a change in analyte level between the first time and the second time.

11. (currently amended) The method of claim 10 wherin the first unit includes a second region responsive to presence of the second level of analyte and the step of bringing the first sample into contact with the first unit includes allowing thesaid second region to indicate whether analyte is present in the sample at at least the second - two sensitivity levels.

12 - 14. (canceled)

15. (previously presented) The method of claim 10 wherein the step of providing the first test unit includes forming thereon at least three regions each responsive to the presence of analyte in the source at a different one of the multiple measurably distinguishable sensitivity levels.

16. (previously presented) The method of claim 15 wherein the step of providing the second test unit includes forming thereon at least three regions each responsive to the presence of analyte in the source at a different one of the multiple measurably distinguishable sensitivity levels.

17. (canceled)

18. (previously presented) The method of claim 16 wherein each of the regions of the first unit is responsive to substantially the same level of analyte as one of the regions of the second unit.

19. (currently amended) The method of claim 10 wherein the step of defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source is accomplished by forming at least the first and second regions.

20. (currently amended) A method for monitoring changes in analyte level of a source, comprising:

providing two or more test units each including multiple regions positioned thereon to receive analyte by capillary flow from a receiving zone, each region in each unit responsive to the presence of an analyte in the source at a sensitivity level measurably distinguishable from another region in the same test unit;

bringing a first sample from the source into contact with a first of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the sample at at least one of the levels; and

on an occasion subsequent to providing the first sample, bringing a second sample from the source into contact with a second of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the second sample at at least one of the levels,

wherein two or more of the regions on each unit are each responsive components in a ligand recognition system to provide different indications of analyte level allowing comparison of responses among regions on different test units based levels of association of a detector reagent with a capture reagent resulting from migration of analyte from an associated receiving zone to the regions by capillary flow

wherein different indications on different test units of presence of analyte in the first and second samples provide evidence as to whether there has been a change in analyte level subsequent to providing the first sample.

21. (previously presented) The method of claim 20 wherein the step of providing one of the test units includes adhesively mounting the multiple regions on a substrate.

22 - 24. (canceled)

25. (currently amended) A method for determining a change in a level of concentration of an analyte present in a source, comprising:

providing multiple unitary test devices, each unitary test device including a plurality of regions, each region being a responsive component in a ligand recognition system, based on capillary flow from a receiving zone, ~~at to~~ a different sensitivity level to indicate presence of the analyte in the source without being determinative of a numerical concentration of the analyte in the source;

on a first occasion, bringing a sample from the source into contact with a first of the unitary test devices to induce a visually observable response thereto in one or more regions of the first test device when the source contains a predetermined minimum level of analyte concentration;

subsequently, on a second occasion, bringing a different sample from the same source into contact with a second of the unitary test devices to induce a visually observable response thereto in one or more regions of the second unitary test device when the source contains a predetermined minimum level of analyte concentration; and

comparing a visually observable response induced in the first test device directly with a visually observable response induced in the second test device to provide information about a change in the level of analyte concentration without requiring determination of analyte concentration in the source on either occasion.

26. (previously presented) The method of claim 25 wherein the first and second test devices are configured to indicate presence of chorionic gonadotrophin as the analyte, and wherein the second occasion is at least one day after the first occasion, the method indicating whether analyte concentration has increased between the first and second occasions.

27. (previously presented) The method of claim 25 wherein the first and second test devices are configured to indicate presence of chorionic gonadotrophin as the analyte, and wherein the second occasion is at least 72 hours after the first occasion, the method indicating whether analyte concentration has doubled between the first and second occasions.

28. (previously presented) The method of claim 10 wherein the step of providing the first and second test units includes forming the first and second units separate and apart from one another.
29. (previously presented) The method of claim 20 wherein the step of providing two or more test units includes forming the test units separate and apart from one another.